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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,014	07/10/2001	Wei-Sing Chu	2313-116	8862
6449 7590 09/19/2007 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER YANG, NELSON C	
			ART UNIT 1641	PAPER NUMBER
			NOTIFICATION DATE 09/19/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

09/901,014

Applicant(s)

CHU, WEI-SING

Examiner

Nelson Yang

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70,72-75,77-79,92-96 and 98-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70,72-75,77-79,92-96 and 98-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 11, 2007 has been entered.

Response to Amendment

2. Applicant's amendment of claims 70, 72-75, 77-79, 92-95, 98-104 is acknowledged and has been entered.

3. Claims 70, 72-75, 77-79, 92-96, 98-104 are currently pending and under examination

Rejections Withdrawn

4. Applicant's arguments, see p.6-9, filed May 11, 2007, with respect to the rejection(s) of claim(s) 70, 72-75, 77-79, 92-96, 98-104 under 35 U.S.C. 102(b) as being anticipated by Northrup et al [US 5,639,423] have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gravlee, Jr. [US 3,961,097] and Ishibashi et al. [US 5,984,881], as discussed below.

Claim Rejections - 35 USC § 103

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 70, 72-75, 77, 78, and 92-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. [US 5,639,423] in view of Gravlee, Jr. [US 3,961,097] and Ishibashi et al. [US 5,984,881].

With respect to claim 70, Northrup et al. teach ultrasonic Lamb-wave devices (abstract) comprising a reactor equipped with a Lamb-wave transducer connected to an inductor (ultrasound transducer and generator) (column 7, lines 29-42) and a Lamb-wave sensor (first sensor) in a reaction chamber (column 7, lines 29-35), wherein the reaction chamber contains a Lamb-wave transducer that acts as an agitator, mixer, or sonochemical inducer (column 7, lines 28-35). Northrup et al. further teach temperature is monitored by measurement of the resistance of polycrystalline layers (column 9, lines 59-64), and also teach sensors for measuring density and viscosity (column 11, lines 40-48), as well as optical detection means (column 6, lines 36-52). Northrup et al. also teach a power source/control system (fig.1, column 6, lines 53-63) for controlling the reaction, either by inductive coupling, capacitive coupling, or by electromagnetic coupling. Detection signals may be processed and stored by integrated microelectronic devices so that result interpretation and control mechanisms can be integrally contained (column 4, lines 40-45). Northrup et al. further disclose that the system may be used to process tissues (column 5, lines 58-60). Northrup et al. do not teach a solution in the reaction chamber for fixing a tissue

sample, nor do Northrup et al. specifically teach a central processing unit that adjusts the frequency or intensity of the ultrasound energy in response to a signal received from the sensor.

Gravlee, Jr., however, teaches that a method for fixing and processing a tissue specimen comprising sequentially immersing the specimen in a fixing agent, a dehydrating agent, a clearing agent, and paraffin while applying ultrasonic energy to the specimen during each of the steps, wherein the specimen and processing agents are contained in a vessel (column 2, lines 1-10). The intensity of application of the energy is controlled during the fixing steps to ensure that cavitation does not occur within the bath (column 2, lines 12-15). Gravlee, Jr. further teaches that the application of ultrasonic energy agitates the agent in the vessel, thus reducing the time required to process the specimen (column 3, lines 42-48).

Therefore, one of ordinary skill in the art at the time of the invention in possession of the ultrasonic device of Northrup et al., when presented with the method disclosed by Gravlee, Jr., would have been motivated to include solutions for fixing a tissue sample in the reaction chamber, in order to reduce the total preparation time needed when fixing and impregnating a tissue specimen in paraffin.

Ishibashi et al. further disclose an ultrasonic therapeutic apparatus comprising a computer (column 25, lines 49-68), which would contain a central processing unit, which controls the power supply for driving the applicator for producing ultrasonic waves (column 25, lines 50-53), as well as an adjusting means feedback from an ultrasonic probe (column 4, lines 5-12 and column 40, lines 20-32). The adjusting means comprises a system controller which may measure and adjust the intensity of the ultrasound (column 16, lines 20-25) as well as include a safeguard

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(column 17, lines 30-37) to ensure that the ultrasound pulses are within an allowable range (column 19, lines 58-65)

Therefore, it would have been obvious to one of ordinary skill in the art to adapt the computer and adjusting means of Ishibashi et al. to the device of Northrup et al. for the purpose of performing the method of Gravlee, Jr., wherein the computer would be capable of adjusting the frequency and intensity of the ultrasound based on feedback from the ultrasound probe to ensure that the ultrasound is within an allowable range, in order to control the application of the ultrasound during the fixing steps to ensure that cavitation does not occur within the bath, as dictated by Gravlee, Jr., thus minimizing damage to the tissue without requiring manual intervention.

7. With respect to claims 72-74, Northrup et al. disclose that the density is measured (column 11, lines 45-47) by monitoring the wave characteristics (which would also allow for measurement of frequency of the ultrasound) using Lamb-wave sensors (column 11, lines 39-42), which are ultrasound sensors.

8. With respect to claim 75, Ishibashi et al. disclose that the computer is capable of processing received signals from the ultrasonic probe (column 25, lines 56-67).

9. With respect to claims 77 and 78, Northrup et al. disclose that the transducer is capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10).

10. With respect to claim 92, Gravlee, Jr. teaches that the fixing agent may be 10% solution of formalin in water (column 3, lines 15-20).

11. With respect to claim 93, Gravlee, Jr. teaches that the dehydrating agent may be an alcohol (column 3, lines 23-25).

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12. With respect to claim 94, Gravlee, Jr. teaches that the clearing agent may be xylene (column 3, lines 25-27).
13. With respect to claim 95, Gravlee, Jr. teaches that the tissue is impregnated with paraffin (column 3, lines 30-32).
14. With respect to claim 96, Northrup et al. teach pumps (LW_1 , LW_2 , LW_3) that pump solution into the reaction chamber and a pump that pumps solution out of the reaction chamber (LW_{DP}) and into the detection chamber (column 7, lines 35-37).
15. Claims 79 and 98-104 rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al. [US 5,639,423] in view of Gravlee, Jr. [US 3,961,097] and Ishibashi et al. [US 5,984,881], as applied to claim 70 above, and further in view of Vago [US 5,665,141].

With respect to claim 79, Northrup et al. do not specifically teach that the transducer produces ultrasound of a power in the range of 0.01-200 W/cm².

Vago, however, teaches a power density of 0.1 to 5 W/cm² (column 3, lines 45-55), and further discloses that the frequency and intensity of the ultrasound should be selected to avoid tissue damaging heating effects (column 7, lines 60-67). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to ensure that the transducers of Northrup et al. are capable producing ultrasound of a power in the range of 0.1 to 5 W/cm² through normal optimization procedures known in the art, in order to avoid tissue-damaging heating effects.

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16. With respect to claim 98, Northrup et al. teach the invention as disclosed above in claim 70. Northrup et al. do not specifically teach that the transducer produces ultrasound of a power in the range of 0.01-200 W/cm².

Vago, however, teaches a power density of 0.1 to 5 W/cm² (column 3, lines 45-55), and further discloses that the frequency and intensity of the ultrasound should be selected to avoid tissue-damaging heating effects (column 7, lines 60-67). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to ensure that the transducers of Northrup et al. are capable producing ultrasound of a power in the range of 0.01-200 W/cm² through normal optimization procedures known in the art, in order to avoid tissue-damaging heating effects.

17. With respect to claim 99, Northrup et al. disclose that the transducer is further capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10).

18. With respect to claims 100-102, the density is measured (column 11, lines 45-47) by monitoring the wave characteristics (which would also allow for measurement of frequency) using Lamb-wave sensors (column 11, lines 39-42), which are ultrasound sensors.

19. With respect to claim 103, Ishibashi et al. disclose that the computer is capable of processing received signal from the ultrasonic probe (column 25, lines 56-67).

20. With respect to claim 104, Northrup et al. teach pumps ((LW₁, LW₂, LW₃) that pump solution into the reaction chamber and a pump that pumps solution out of the reaction chamber (LW_{DP}) and into the detection chamber (column 7, lines 35-37).

Response to Arguments

21. Applicant's arguments with respect to claims 70, 72-75, 77-79, 92-96, and 98-104 have been considered but are moot in view of the new ground(s) of rejection. The following argument, however, has been addressed.

22. With respect to applicant's argument that Northrup et al. fails to teach that the transducer generates ultrasound of a frequency of at least 100 KHz (or 0.1 MHz), Northrup et al. discloses that the transducer is capable of producing Lamb waves with frequencies from 1 to 200 MHz (column 11, lines 3-10), which are all frequencies greater than 100 KHz. Since the limitation at least 100 KHz would indicate any frequency greater than or equal to 100 KHz, the limitation is anticipated, and applicant's argument is not found persuasive.

Conclusion

23. No claims are allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Nelson Yang
Patent Examiner
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